Vaccination over Parental Objection — Should Adolescents Be Allowed to Consent to Receiving Vaccines?

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The United States has been experiencing an increasing number of measles outbreaks, and more measles cases were reported in the first 5 months of 2019 than in any full year since 1992, which was 8 years before endemic transmission was interrupted. Parents' resistance to vaccination is leaving more children vulnerable to measles and various other preventable illnesses. Some of these children have begun to seek opportunities to revisit vaccine-refusal decisions made on their behalf by their parents and are now pursuing vaccination.

In a March 2019 congressional hearing on preventable disease outbreaks, Ohio high school senior Ethan Lindenberger shared his experience of trying to get vaccinated over his mother's objections. Lindenberger testified that his mother is an antivaccine advocate who believes that vaccines can cause autism and brain damage, "despite the fact such opinions have been debunked numerous times by the scientific community."[1] Once he turned 18, Lindenberger went to a public health clinic for vaccinations against hepatitis A and B, influenza, and human papillomavirus (HPV).

Such cases raise the question of whether adolescent minors should be able to consent to vaccinations without parental permission. For minors to be able to choose to be vaccinated over parental objections, most states would need to make substantive changes to laws governing medical consent. Since children are generally considered nonautonomous under U.S. law, treatment of a child in a medical setting requires parental permission, typically until a child reaches 18 years of age. Parents are generally given broad discretion in making decisions on behalf of their children, in part because they know their child best, are positioned to weigh competing family interests, and are permitted to raise their child as they choose. Such discretion doesn't mean that adolescents have no role in decisions that affect them, however. Out of respect for adolescents' developing autonomy, clinicians routinely explore their understanding of health-related issues, solicit their agreement on care plans, navigate discordance between parental and adolescent preferences, and protect adolescents' confidentiality interests.[2]

Both ethical principles and state laws also support independent decision making by adolescents in cases in which failing to grant adolescents autonomy could foreseeably result in substantial risk to the minor or to public health. For instance, all states have laws permitting minors to make independent, confidential clinical decisions regarding certain sensitive or stigmatized health care services, such as those related to sexual health, reproduction, mental health, and substance use disorders. Roughly 20% of jurisdictions require adolescents to be at least 12 or 14 years of age to make such decisions; others don't designate a minimum age of consent.[3] A court may also grant an older adolescent (typically 16 years or older) legal emancipation or deem the adolescent to be a "mature minor" who is able to make certain decisions independently.

Most states, however, don't authorize adolescents to independently consent to vaccination. Under consent-related rules for sensitive or stigmatized health care services, several jurisdictions, such as California and New York, allow adolescents to make decisions regarding prevention of sexually transmitted infections (STIs), which includes acceptance of hepatitis B and HPV vaccines (see table).[3] Idaho allows adolescents to make independent medical decisions when a clinician believes the minor is capable of fulfilling informed-consent responsibilities. At least three other states permit adolescents to make a broad array of autonomous clinical decisions, including regarding vaccination (Alabama at 14 years of age, Oregon at 15, and South Carolina at 16). Alaska allows minors to make independent decisions when a parent "is unwilling either to grant or withhold consent."

Bills have been proposed in at least two jurisdictions in 2019 to grant adolescents independent authority to consent to vaccination. New York's bill would allow anyone 14 or older to consent to any vaccine required for school or day care entry (measles–mumps–rubella, diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, varicella, and meningitis vaccines). A bill in Washington, D.C., would permit any minor deemed by a clinician to be capable of meeting informed-consent standards

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Statutes and Bills Regarding Adolescents' Consent to Treatment.*

State	Bill or Law (Citation)	Minimum Age	Consent to STI-Related Vaccines Only	Consent to Any Required Vaccines	Consent to Any ACIP-Recommended Vaccines	Consent to Any Health Care, Including Vaccination
New York	Bill (A06564)	14 yr		X		
District of Columbia	Bill (B23-0171)	None, as long as minor is capable of meeting informed-consent standards			X	
California	Law (CA Family Code 6926)	12 yr	X			
Delaware	Law (Del. Code Ann. tit. 13, § 710)	12 yr	X			
District of Columbia	Law (D.C. Mun. Regs. tit. 22, § 600.7)	None	X			
Minnesota	Law (Minn. Stat. § 144.3441)	None	X†			
New York	Law (NY Consol. Laws PBH § 2305, 10 NYCRR 23.4)	None	X			
Alaska	Law (AS 25.20.025)	None, when parent or guardian "is unwilling either to grant or withhold consent"				X
Idaho	Law (ID Code 39-4503)	None, as long as minor is capable of meeting informed-consent standards				X
Alabama	Law (AL Code 22-8-4)	14 yr				X
Oregon	Law (2017 ORS 109.640)	15 yr				X
South Carolina	Law (SC 63-5-340)	16 yr				X

* Abortion-related care is not included under Alaska's law. Under South Carolina's law, no consent other than the minor's is needed unless providers believe proposed health services are "essential to the health or life of (the) child." ACIP denotes the Advisory Committee on Immunization Practices, and STI sexually transmitted infection.
† Hepatitis B only.

for care to consent to any vaccine recommended by the Advisory Committee on Immunization Practices, which includes HPV and annual influenza vaccines along with those covered in New York's bill.

Granting adolescents the authority to agree to vaccination without parental permission would allow them to catch up on any missed childhood vaccines. Although not a panacea for all vaccine uptake and access problems, such laws could improve rates of vaccination against highly infectious diseases such as measles. They may be particularly relevant for vaccines recommended for adolescents owing to the lack of regular preventive care visits among this group.[4] Adolescents could receive vaccines in alternative settings, such as pharmacies, which may be more accessible than health care offices in rural areas, or school health clinics. Consent requirements can also be a barrier to vaccination in alternative settings, however. For instance, some state laws constrain pharmacists from vaccinating patients younger than 18, and some schools require consent from parents to vaccinate children.

If minors are authorized to consent to vaccination, at what age should this right be granted? Although a broad guideline deferential to clinical judgment, as is outlined in the bill being considered in Washington, D.C., offers maximal flexibility, it also seems prudent to link consent to vaccination to a specific age at which minors are already granted decision-making authority. This cutoff could be as early as 12, in keeping with the age at which many states grant minors decision-making authority for STI-related services, or 14, as it is under Alabama's broader law on clinical decision making. Setting an explicit age would provide a more just and clear implementation standard for all adolescents and the clinicians treating them. On average, professionals responding to a recent survey reported that they were comfortable with patients at least 14 years of age consenting to vaccines recommended for adolescents, including vaccines against pertussis, meningitis, HPV, and influenza.[5]

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Granting minors decision-making authority for vaccination also triggers reconsideration of the materials and associated communication needed to ensure that they can make informed decisions. Federal law requires that clinicians provide adult patients and children's parents or legal representatives with a Vaccine Information Sheet before vaccination. Since such materials are written at a 10th-grade reading level, they would most likely require revision if intended recipients were to include adolescents as young as 12 or 14 years of age.

Parental involvement in vaccination decisions remains important. Many vaccine-hesitant parents ultimately agree to vaccination. Yet adolescents need not be harmed by parental decisions that are based on misinformation or disinformation. Allowing adolescents to consent to vaccination despite persistent parental resistance facilitates access to a medically recommended and evidence-based treatment. It promotes the minor's health, poses minimal personal risk, and offers substantial prosocial benefits, including reinforcement of the norm of vaccination and enhancement of community protection against the spread of dangerous and costly yet preventable diseases. Given such benefits, we believe that states should enact laws that expand both access to vaccines and the rights of minors who are at least 12 to 14 years of age to consent to vaccination.

Disclosure forms provided by the authors are available at NEJM.org.

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Reforming the Orphan Drug Act for the 21st Century

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Congress passed the Orphan Drug Act in 1983 to spur development of drugs to treat rare diseases. Among the law's incentives were exclusive marketing rights for 7 years for the rare-disease indication ("orphan drug exclusivity"), a 50% tax credit for costs associated with the clinical testing of such drugs (reduced to 25% in 2017), and grants for clinical trials. There has since been a marked increase in the number of drugs approved by the Food and Drug Administration (FDA) for rare diseases. Between 1983 and 2017, a total of 487 orphan-designated drugs entered the U.S. market.[1] In 2018, of the new drugs approved, 58% (34 of 59) were for a rare-disease indication.

At the same time, there has been growing concern that the Orphan Drug Act has been subject to gaming. The most recent controversy occurred in December 2018, when Catalyst Pharmaceuticals announced that it would price amifampridine (Firdapse), a treatment for the rare neuromuscular disease Lambert–Eaton myasthenic syndrome, at $375,000 per year. Although the FDA had approved Catalyst's product as an orphan-designated drug in November 2018, amifampridine was not new. It had been marketed in the United Kingdom since 2010 at an annual price of less than £30,000 (about $40,000) per patient and was available to U.S. patients with the syndrome for free under an expanded-access program. In February 2019, Senator Bernie Sanders (I-VT) brought attention to this case and asked Catalyst to explain its pricing decision. The company responded in part by arguing that amifampridine's price is in line with that of other products used to treat rare, severe diseases.

In recent years, several manufacturers have earned hundreds of millions of dollars in annual revenue from rare-disease drugs. The cystic fibrosis treatment lumacaftor–ivacaftor (Orkambi), the idiopathic pulmonary fibrosis treatment pirfenidone (Esbriet), and the spinal muscular atrophy treatment nusinersen (Spinraza) each generated more than $1 billion in sales in 2018. Such cases raise the question of whether the

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